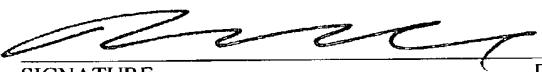


JLDS Rec'd PCT/PQ 01 MAR 2002

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (REV. 12-2001)		ATTORNEY'S DOCKET NUMBER 22748/1
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/070271</b>
INTERNATIONAL APPLICATION NO. PCT/GB00/04288	INTERNATIONAL FILING DATE 8 November 2000	PRIORITY DATE CLAIMED 11 November 1999
TITLE OF INVENTION ANKLE/FOOT ORTHOSIS		
APPLICANT(S) FOR DO/EO/US NICKSON		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input checked="" type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)). a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made, however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
<b>Items 11 to 20 below concern document(s) or information included:</b>		
<p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included</p> <p>13. <input checked="" type="checkbox"/> A <b>FIRST</b> preliminary amendment</p> <p>14. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</p> <p>15. <input checked="" type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 – 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input type="checkbox"/> Other items or information:</p>		

U.S. APPLICATION NO. (or int'l filing, see 37 CFR 1.1) <b>101070271</b>		INTERNATIONAL APPLICATION NO PCT/GB00/04288	ATTORNEY'S DOCKET NUMBER 22748/1
21. <input checked="" type="checkbox"/> The following fees are submitted:		<b>CALCULATIONS</b>	PTO USE ONLY
<b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b>			
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. .... <b>\$1040.00</b>			
International preliminary examination fee ((37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO..... <b>\$890.00</b>			
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO..... <b>\$740.00</b>			
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... <b>\$710.00</b>			
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). . . . . <b>\$100.00</b>			
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> \$890.00			
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).			
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	13 - 20 =	0	x <b>\$ 18.00</b>
Independent claims	1 - 3 =	0	x <b>\$ 84.00</b>
<b>MULTIPLE DEPENDENT CLAIM(S) (if applicable)</b>		+ \$280.00	\$ 0
<b>TOTAL OF ABOVE CALCULATIONS =</b> \$890.00			
<input type="checkbox"/> Applicant claims small entity status See 37 CFR 1.27. The fees indicated above are reduced by ½ +			
<b>SUBTOTAL =</b> \$890.00			
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			
<b>TOTAL NATIONAL FEE =</b> \$890.00			
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property.			
<b>TOTAL FEES ENCLOSED =</b> \$890.00			
<b>Amount to be refunded:</b> \$			
<b>Charged:</b> \$			
a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.			
b. <input checked="" type="checkbox"/> Please charge by Deposit Account No. <u>50-0369</u> in the amount of \$ <u>890.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.			
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No <u>50-0369</u> . A duplicate copy of this sheet is enclosed.			
d. <input type="checkbox"/> Fees are to be charged to a credit card <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.			
<b>NOTE: Where an appropriate time limit under CFT 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</b>			
SEND ALL CORRESPONDENCE TO:			
 <b>Mark S. Leonardo</b> Registration No. 41,433 Attorney for Applicants Brown Rudnick Berlack Israels LLP Customer No. 21710 One Financial Center, Boston, MA 02111 Tel: (617) 856 8396 Fax: (617) 856 8201			
SIGNATURE <span style="float: right;">Date <u>3/1/02</u></span> <hr/> <b>Mark S. Leonardo</b> NAME <hr/> 41,433 REGISTRATION NUMBER			

10/070271

JC19 Rec'd PCT/PTO 01 MAR 2002

Docket No.: 22748/1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT(S):** NICKSON

**EXAMINER:** TBA

**SERIAL NO.:** PCT/GB00/04288

**ART UNIT:** TBA

**FILED:** February 28, 2002

**FOR:** ANKLE/FOOT ORTHOSIS

**CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as U.S. express mail in an envelope addressed to BOX PCT, Assistant Commissioner of Patents and Trademarks, Washington, DC 20231 on

Date 1/31/02

By   
Angela Robinson

BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Sir:

Please amend the specification for the U.S. National Phase of the present International Patent Application by substituting the attached substitute specification and claims.

**IN THE SPECIFICATION**

Please substitute the specification attached in Appendix I for the previously filed specification. Applicant submits that no new matter is added and that the only changes are the addition of section headings at the appropriate locations in the specification according to U.S. practice. A marked-up copy of the original specification is attached in Appendix II pursuant to 37 CFR 1.121 (b)(3)(iii).

**IN THE CLAIMS**

Please cancel claims 1 – 12.

Please add the following new claims 13 – 25.

13. An ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal stiffener, a sole plate, and a strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle, wherein said strut is flexible.

14. An ankle/foot orthosis according to claim 13 wherein the flexible portions of the orthosis are manufactured substantially of one of glass fibre and aramid fibre reinforced resin, and the inflexible portion is manufactured in carbon fibre reinforced resin.

15. An ankle/foot orthosis according to claim 13 wherein the rigidity of sole plate varies over the area thereof, portions being inflexible, and portions being flexible so as to give support to the foot whilst allowing bending of the toes.

16. An ankle/foot orthosis according to claim 14 wherein the rigidity of sole plate varies over the area thereof, portions being inflexible, and portions being flexible so as to give support to the foot whilst allowing bending of the toes.

17. An ankle/foot orthosis according to claim 13 wherein the strapping member is adapted to extend around the sides of a leg, and has securing straps adapted to accommodate variation in leg thickness.
18. An ankle/foot orthosis according to claim 17 wherein said strapping member is moulded from a soft thermoplastic so as to be mouldable by application of heat
19. An ankle/foot orthosis according to claim 13 wherein said strut is encased.
20. An ankle/foot orthosis according to claim 19 wherein the strut is encased in sleeve of plastics material.
21. An ankle/foot orthosis according to claim 20 wherein said sleeve is heat shrinkable so as to mould itself tightly to the contours of the strut.
22. An ankle/foot orthosis according to claim 13 wherein fasteners are provided whereby the stiffener is movable longitudinally of the strapping member
23. An ankle/foot orthosis according to claim 22 wherein said stiffener is on the inside of said strapping member.
24. An ankle/foot orthosis according to claim 13 wherein said stiffener resides in a channel of the strapping member.
25. An ankle/foot orthosis according to claim 24 wherein said channel is open at the bottom.

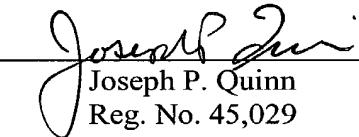
**REMARKS**

Applicant submits that no new matter has been added by the present amendments. Rather, the amendments herein are intended to place the internationally filed application in form for U.S. prosecution.

Please charge any deficiency as well as any other fee(s) which may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

Respectfully submitted,

March 3, 2001  
Dated

  
\_\_\_\_\_  
Joseph P. Quinn  
Reg. No. 45,029  
Customer No. 21710  
Attorney for Applicants

**BROWN, RUDNICK, BERLACK, ISRAELS L.L.P.**  
Box IP, 18th Floor  
One Financial Center  
Boston, MA 02111  
Tel: 1-617-856-8369  
Fax: 1-617 856-8201

## APPENDIX I

### Background of the Invention

This invention relates to an ankle foot orthosis intended to support the lower leg, ankle and foot. Such an orthosis may be required in order to counteract the effects of muscular and nervous disorders.

### Summary of the Invention

Conventional orthoses provide a rather rigid strut or frame which is fixed to the lower leg and foot in order to counter the effect of e.g. muscle spasms therein. When fitted, the patient may be able to walk whereas without an orthosis, walking may be almost impossible.

A traditional orthosis is somewhat bulky, and may require the wearing of special clothing and shoes. An additional and significant disadvantage is that a normal walking gait cannot be obtained due to the inevitable immobilisation of at least part of the ankle joint.

WO-A-9834572 proposes an ankle/foot orthosis having a rigid strut connecting a lower leg support to a sole plate. The strut is generally inflexible, but the sole plate is said to have sufficient flexibility to improve the walking gait by permitting bending of the toes.

According to the present invention there is provided an ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal stiffener, a sole plate, and a relatively flexible strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle.

Such an orthosis is flexible in the region of the ankle, and thus permits a degree of ankle flexibility, which promotes a more normal walking gait.

In this specification the terms flexible and inflexible are relative, and will be understood by the skilled man in relation to ankle/foot orthoses. Generally speaking, a flexible member has the degree of flexibility imparted by glass reinforced plastic resin (grp), whereas an inflexible member has the degree of flexibility imparted by a carbon fibre reinforced plastic resin. In terms of ankle movement, an inflexible member would prevent any substantial ankle movement in the plane or planes intended to be rigidified, whereas a flexible member would permit a degree of movement.

Preferably the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the rigid portion is manufactured in carbon fibre reinforced resin. Such a construction permits integration of the fibres during the lay-up stage of manufacture, thus giving a substantially seamless resilient product after curing.

The rigidity of sole plate is preferably variable over the area thereof, portions being relatively rigid, and portions being relatively flexible so as to give support to the foot whilst allowing bending of the toes.

The strapping member preferably extends around the sides of the leg and has securing straps to accommodate variation in leg thickness. Preferably this strapping member is moulded from a soft thermoplastic so as to be mouldable by application of heat. Thermoplastic also facilitates easy trimming to fit a patient, for example by scissors.

The flexible strut is preferably encased for protection against impact damage, and to reduce abrasion. The encasement may be a sleeve of plastics material, which is preferably heat shrinkable so as to mould itself tightly to the contours of the strut.

Fasteners may be provided whereby the stiffener is movable longitudinally of the strapping member, so as to facilitate comfortable fitment to persons of different leg length.

The stiffener is preferably on the inside of the strapping member, and in a preferred embodiment resides in a channel formed therein. The channel is preferably open at the bottom.

#### **Brief Description of the Drawings**

Other features of the invention will be apparent from the following description of a preferred embodiment, shown by way of example only in the accompany drawings in which:

Figure 1 is a side elevation of the lower leg and foot of a human, to which an orthosis according to the invention has been attached;

Figure 2 is a front elevation of an unattached orthosis corresponding to Figure 1; and

Figure 3 is a graphical representation showing the gait provided by the invention.

#### **Detailed Description of the Drawings**

With reference to the drawings, an orthosis 10 comprises a strapping member 11 of

thermoplastic and typically having a thickness of 2.5mm. This member is sufficiently rigid to be self-supporting in a shape conforming approximately to the front and side contours of a human leg 12. The member is also mouldable by the application of heat, for example from a hot air gun, in order to obtain a good fit around a patient's leg. The sides of the supporting member are cut away to improve comfort, leaving four strapping regions which extend further round the leg. On the left side of Figure 2 (as viewed) simple buckles 13 are attached by fabric loops 14 and rivets 15. On the right side, fabric straps 16 having inner end and outer end areas 17, 18 covered with the different components of a suitable hook and loop type of fastener. The straps 16 are also attached by rivets 15.

Moulded within the member 11 is a channel 19 open at the bottom and generally aligned with the shin bone.

Closely fitting within the channel 19 is a stiffener 21 of carbon fibre reinforced resin. Typically the stiffener has a width of about 26mm, and a thickness of 3mm.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be solely of glass fibre to permit relatively easy trimming to size thereof.

The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in

the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless construction.

The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 22 by rivets or screws 24. A plurality of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit, the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

Thereafter the strapping portion is attached, after suitable measurement of a patient. Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel

strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of walking normally. The overall time for a step at normal walking pace is about the same as for an undischarged person, thus permitting an approximately even walking pace where only one leg of the person requires support.

Various modification to the embodiment will occur to the skilled man within the scope of the appended claims and without departing from the essence of the present invention.

### **Abstract**

An ankle/foot orthosis has a strapping member for the lower leg, an inflexible anterior longitudinal stiffener, a sole plate, and a relatively flexible strut connecting the stiffener to the sole plate. The flexible strut permits a degree of ankle flexibility, and promotes a more natural walking gait.

## APPENDIX II

### Background of the Invention

This invention relates to an ankle foot orthosis intended to support the lower leg, ankle and foot. Such an orthosis may be required in order to counteract the effects of muscular and nervous disorders.

### Summary of the Invention

Conventional orthoses provide a rather rigid strut or frame which is fixed to the lower leg and foot in order to counter the effect of e.g. muscle spasms therein. When fitted, the patient may be able to walk whereas without an orthosis, walking may be almost impossible.

A traditional orthosis is somewhat bulky, and may require the wearing of special clothing and shoes. An additional and significant disadvantage is that a normal walking gait cannot be obtained due to the inevitable immobilisation of at least part of the ankle joint.

WO-A-9834572 proposes an ankle/foot orthosis having a rigid strut connecting a lower leg support to a sole plate. The strut is generally inflexible, but the sole plate is said to have sufficient flexibility to improve the walking gait by permitting bending of the toes.

According to the present invention there is provided an ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal stiffener, a sole

plate, and a relatively flexible strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle.

Such an orthosis is flexible in the region of the ankle, and thus permits a degree of ankle flexibility, which promotes a more normal walking gait.

In this specification the terms flexible and inflexible are relative, and will be understood by the skilled man in relation to ankle/foot orthoses. Generally speaking, a flexible member has the degree of flexibility imparted by glass reinforced plastic resin (grp), whereas an inflexible member has the degree of flexibility imparted by a carbon fibre reinforced plastic resin. In terms of ankle movement, an inflexible member would prevent any substantial ankle movement in the plane or planes intended to be rigidified, whereas a flexible member would permit a degree of movement.

Preferably the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the rigid portion is manufactured in carbon fibre reinforced resin. Such a construction permits integration of the fibres during the lay-up stage of manufacture, thus giving a substantially seamless resilient product after curing.

The rigidity of sole plate is preferably variable over the area thereof, portions being relatively rigid, and portions being relatively flexible so as to give support to the foot whilst allowing bending of the toes.

The strapping member preferably extends around the sides of the leg and has securing straps to accommodate variation in leg thickness. Preferably this strapping member is moulded from a

soft thermoplastic so as to be mouldable by application of heat. Thermoplastic also facilitates easy trimming to fit a patient, for example by scissors.

The flexible strut is preferably encased for protection against impact damage, and to reduce abrasion. The encasement may be a sleeve of plastics material, which is preferably heat shrinkable so as to mould itself tightly to the contours of the strut.

Fasteners may be provided whereby the stiffener is movable longitudinally of the strapping member, so as to facilitate comfortable fitment to persons of different leg length.

The stiffener is preferably on the inside of the strapping member, and in a preferred embodiment resides in a channel formed therein. The channel is preferably open at the bottom.

#### **Brief Description of the Drawings**

Other features of the invention will be apparent from the following description of a preferred embodiment, shown by way of example only in the accompany drawings in which:

Figure 1 is a side elevation of the lower leg and foot of a human, to which an orthosis according to the invention has been attached;

Figure 2 is a front elevation of an unattached orthosis corresponding to Figure 1; and

Figure 3 is a graphical representation showing the gait provided by the invention.

### **Detailed Description of the Drawings**

With reference to the drawings, an orthosis 10 comprises a strapping member 11 of thermoplastic and typically having a thickness of 2.5mm. This member is sufficiently rigid to be self-supporting in a shape conforming approximately to the front and side contours of a human leg 12. The member is also mouldable by the application of heat, for example from a hot air gun, in order to obtain a good fit around a patient's leg. The sides of the supporting member are cut away to improve comfort, leaving four strapping regions which extend further round the leg. On the left side of Figure 2 (as viewed) simple buckles 13 are attached by fabric loops 14 and rivets 15. On the right side, fabric straps 16 having inner end and outer end areas 17, 18 covered with the different components of a suitable hook and loop type of fastener. The straps 16 are also attached by rivets 15.

Moulded within the member 11 is a channel 19 open at the bottom and generally aligned with the shin bone.

Closely fitting within the channel 19 is a stiffener 21 of carbon fibre reinforced resin. Typically the stiffener has a width of about 26mm, and a thickness of 3mm.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be

solely of glass fibre to permit relatively easy trimming to size thereof.

The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless construction.

The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 22 by rivets or screws 24. A plurality of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit, the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

Thereafter the strapping portion is attached, after suitable measurement of a patient. Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of walking normally. The overall time for a step at normal walking pace is about the same as for an undischarged person, thus permitting an approximately even walking pace where only one leg of the person requires support.

Various modification to the embodiment will occur to the skilled man within the scope of the appended claims and without departing from the essence of the present invention.

### Abstract

An ankle/foot orthosis has a strapping member for the lower leg, an inflexible anterior longitudinal stiffener, a sole plate, and a relatively flexible strut connecting the stiffener to the sole plate. The flexible strut permits a degree of ankle flexibility, and promotes a more natural walking gait.

10/070271

PCT/GB00/04288

WO 01/34071

1 Rec'd PCT/PTC 0 1 MAR 2002

## ANKLE FOOT ORTHOSIS

- 5 This invention relates to an ankle foot orthosis intended to support the lower leg, ankle and foot. Such an orthosis may be required in order to counteract the effects of muscular and nervous disorders.

Conventional orthoses provide a rather rigid strut or frame which is fixed to the lower 10 leg and foot in order to counter the effect of e.g. muscle spasms therein. When fitted, the patient may be able to walk whereas without an orthosis, walking may be almost impossible.

A traditional orthosis is somewhat bulky, and may require the wearing of special 15 clothing and shoes. An additional and significant disadvantage is that a normal walking gait cannot be obtained due to the inevitable immobilisation of at least part of the ankle joint.

WO-A-9834572 proposes an ankle/foot orthosis having a rigid strut connecting a lower 20 leg support to a sole plate. The strut is generally inflexible, but the sole plate is said to have sufficient flexibility to improve the walking gait by permitting bending of the toes.

According to the present invention there is provided an ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal 25 stiffener, a sole plate, and a relatively flexible strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle.

Such an orthosis is flexible in the region of the ankle, and thus permits a degree of 30 ankle flexibility, which promotes a more normal walking gait.

In this specification the terms flexible and inflexible are relative, and will be understood by the skilled man in relation to ankle/foot orthoses. Generally speaking, a flexible member has the degree of flexibility imparted by glass reinforced plastic resin (grp), whereas an inflexible member has the degree of flexibility imparted by a carbon fibre  
5 reinforced plastic resin. In terms of ankle movement, an inflexible member would prevent any substantial ankle movement in the plane or planes intended to be rigidified, whereas a flexible member would permit a degree of movement.

Preferably the flexible portions of the orthosis are manufactured substantially of glass  
10 fibre or aramid fibre reinforced resin, and the rigid portion is manufactured in carbon fibre reinforced resin. Such a construction permits integration of the fibres during the lay-up stage of manufacture, thus giving a substantially seamless resilient product after curing.

15 The rigidity of sole plate is preferably variable over the area thereof, portions being relatively rigid, and portions being relatively flexible so as to give support to the foot whilst allowing bending of the toes.

The strapping member preferably extends around the sides of the leg and has securing  
20 straps to accommodate variation in leg thickness. Preferably this strapping member is moulded from a soft thermoplastic so as to be mouldable by application of heat. Thermoplastic also facilitates easy trimming to fit a patient, for example by scissors.

25 The flexible strut is preferably encased for protection against impact damage, and to reduce abrasion. The encasement may be a sleeve of plastics material, which is preferably heat shrinkable so as to mould itself tightly to the contours of the strut.

Fasteners may be provided whereby the stiffener is movable longitudinally of the strapping member, so as to facilitate comfortable fitment to persons of different leg  
30 length.

The stiffener is preferably on the inside of the strapping member, and in a preferred embodiment resides in a channel formed therein. The channel is preferably open at the bottom.

- 5 Other features of the invention will be apparent from the following description of a preferred embodiment, shown by way of example only in the accompany drawings in which:

10 Figure 1 is a side elevation of the lower leg and foot of a human, to which an orthosis according to the invention has been attached;

Figure 2 is a front elevation of an unattached orthosis corresponding to Figure 1; and

Figure 3 is a graphical representation showing the gait provided by the invention.

15

With reference to the drawings, an orthosis 10 comprises a strapping member 11 of thermoplastic and typically having a thickness of 2.5mm. This member is sufficiently rigid to be self-supporting in a shape conforming approximately to the front and side contours of a human leg 12. The member is also mouldable by the application of heat, 20 for example from a hot air gun, in order to obtain a good fit around a patient's leg. The sides of the supporting member are cut away to improve comfort, leaving four strapping regions which extend further round the leg. On the left side of Figure 2 (as viewed) simple buckles 13 are attached by fabric loops 14 and rivets 15. On the right side, fabric straps 16 having inner end and outer end areas 17, 18 covered with the different 25 components of a suitable hook and loop type of fastener. The straps 16 are also attached by rivets 15.

Moulded within the member 11 is a channel 19 open at the bottom and generally aligned with the shin bone.

30

Closely fitting within the channel 19 is a stiffener 21 of carbon fibre reinforced resin. Typically the stiffener has a width of about 26mm, and a thickness of 3mm.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of  
5 selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be solely of glass fibre to permit relatively easy trimming to size thereof.

10

The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless  
15 construction.

The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 11 by rivets or screws 24. A plurality  
20 of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit,  
25 the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

Thereafter the strapping portion is attached, after suitable measurement of a patient.  
30 Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

- 5      Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of  
10     walking normally. The overall time for a step at normal walking pace is about the same as for an undischarged person, thus permitting an approximately even walking pace where only one leg of the person requires support.

Various modification to the embodiment will occur to the skilled man within the scope  
15     of the appended claims.

**Claims****CLAIMS**

- 5      1. An ankle/foot orthosis comprising a strapping member (11) for a lower leg, and having an inflexible anterior longitudinal stiffener (21), a sole plate (23), and a strut (22) connecting the longitudinal stiffener (21) and the sole plate (23), the strut (22) extending to the sole plate (23) at the outer side thereof, and anterior of the position of the ankle, characterized in that said strut (22) is flexible.
- 10     2. An ankle/foot orthosis according to claim 1 wherein the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the inflexible portion is manufactured in carbon fibre reinforced resin.
- 15     3. An ankle/foot orthosis according to claim 1 or claim 2 wherein the rigidity of sole plate (23) varies over the area thereof, portions being inflexible, and portions being flexible so as to give support to the foot whilst allowing bending of the toes.
- 20     4. An ankle/foot orthosis according to any preceding claim wherein the strapping member (11) is adapted to extend around the sides of a leg, and has securing straps adapted to accommodate variation in leg thickness.
- 25     5. An ankle/foot orthosis according to claim 4 wherein said strapping member (11) is moulded from a soft thermoplastic so as to be mouldable by application of heat
6. An ankle/foot orthosis according to any preceding claim wherein said strut (22) is encased.
- 30     7. An ankle/foot orthosis according to claim 6 wherein the strut (22) is encased in a sleeve of plastics material.
8. An ankle/foot orthosis according to claim 7 wherein said sleeve is heat shrinkable so as to mould itself tightly to the contours of the strut (22).

9. An ankle/foot orthosis according to any preceding claim wherein fasteners (24) are provided whereby the stiffener (21) is movable longitudinally of the strapping member (11).

5

10. An ankle/foot orthosis according to claim 9 wherein said stiffener (21) is on the inside of said strapping member (11).

11. An ankle/foot orthosis according to claim 10 wherein said stiffener (21) resides in  
10 a channel (19) of the strapping member (11).

12. An ankle/foot orthosis according to claim 11 wherein said channel (19) is open at the bottom.

15

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
17 May 2001 (17.05.2001)

PCT

(10) International Publication Number  
**WO 01/34071 A1**

(51) International Patent Classification<sup>7</sup>: **A61F 5/01**

(21) International Application Number: PCT/GB00/04288

(22) International Filing Date:  
8 November 2000 (08.11.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
9926599.3 11 November 1999 (11.11.1999) GB

(71) Applicant (for all designated States except US): **TYCO  
HEALTHCARE UK LIMITED [GB/GB]**; 154 Fareham  
Road, Gosport, Hampshire PO13 OAS (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **NICKSON, Shane,  
Willard [GB/GB]**; 54 Glenorchy Road, Carterknowle,  
Sheffield S7 2EL (GB).

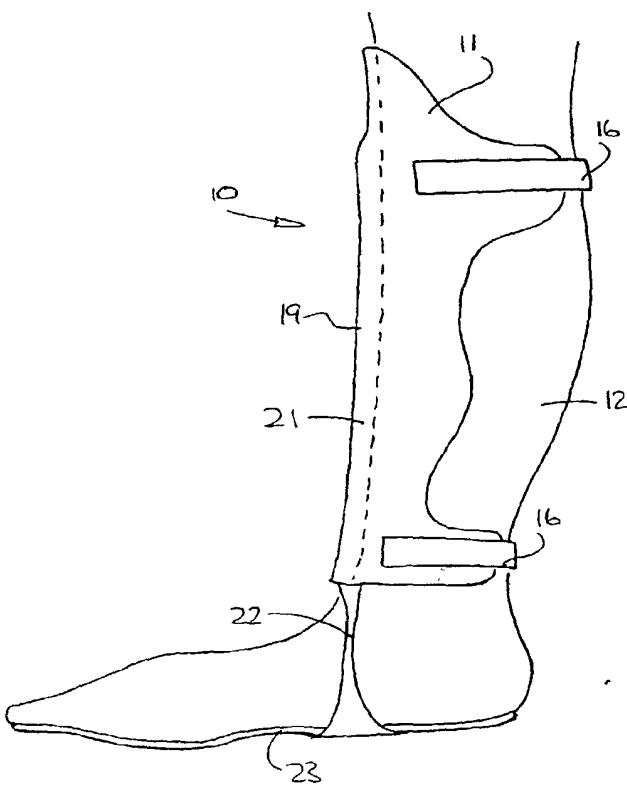
(74) Agents: **CHETTLE, Adrian, John et al.**; Withers &  
Rogers, Goldings House, 2 Hays Lane, London SE1 2HW  
(GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,  
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,  
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,  
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,  
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,  
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

[Continued on next page]

(54) Title: ANKLE/FOOT ORTHOSIS



(57) Abstract: An ankle/foot orthosis (10) has a strapping member (11) for the lower leg, an inflexible anterior longitudinal stiffener (21), a sole plate (23), and a relatively flexible strut (22) connecting the stiffener (21) to the sole plate (23). The flexible strut (22) permits a degree of ankle flexibility, and promotes a more natural walking gait.

WO 01/34071 A1

10/070271

PCT/GB00/04288

WO 01/34071

1 / 3

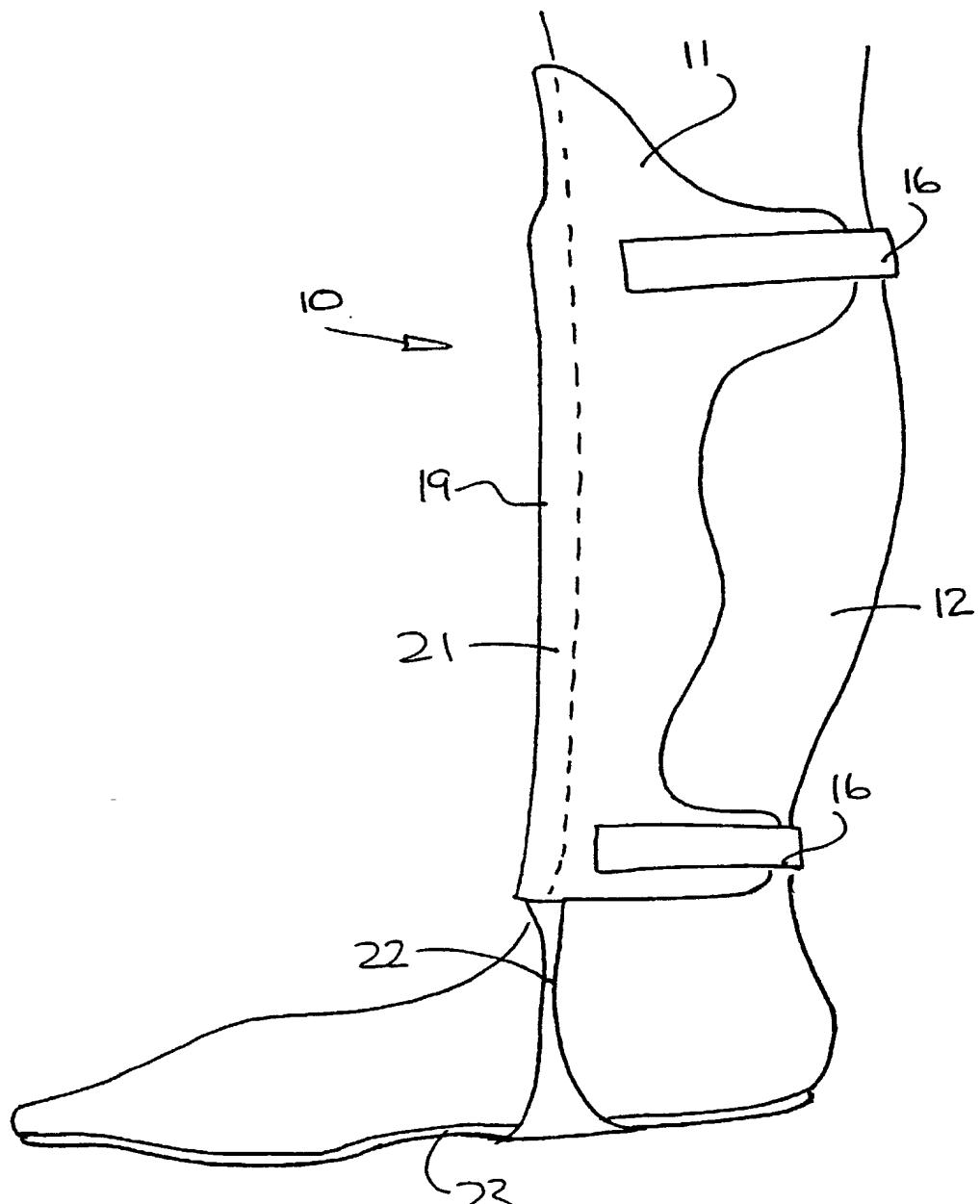
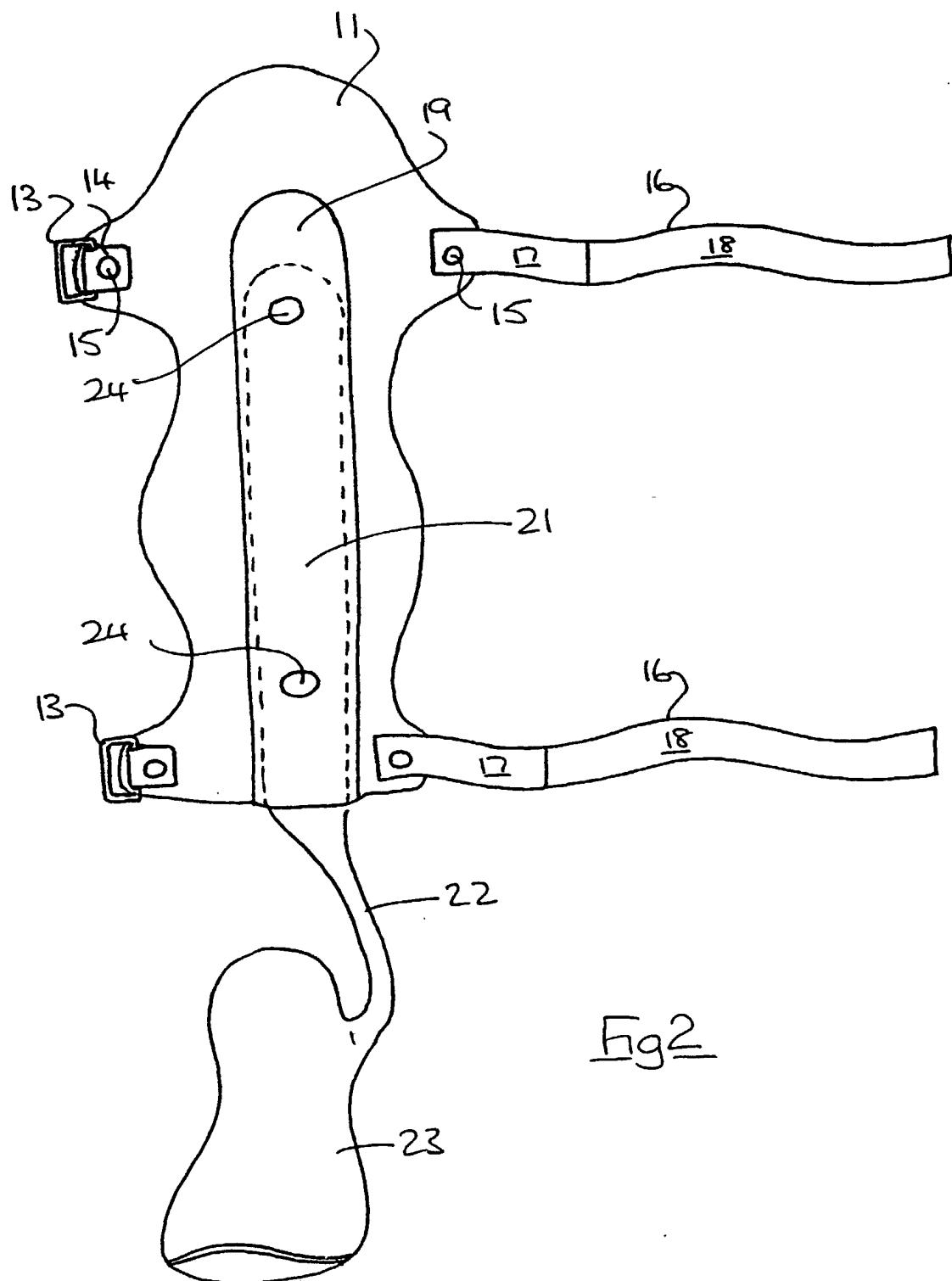


Fig 1



10/07/2021

PCT/GB00/04288

WO 01/34071

3 / 3

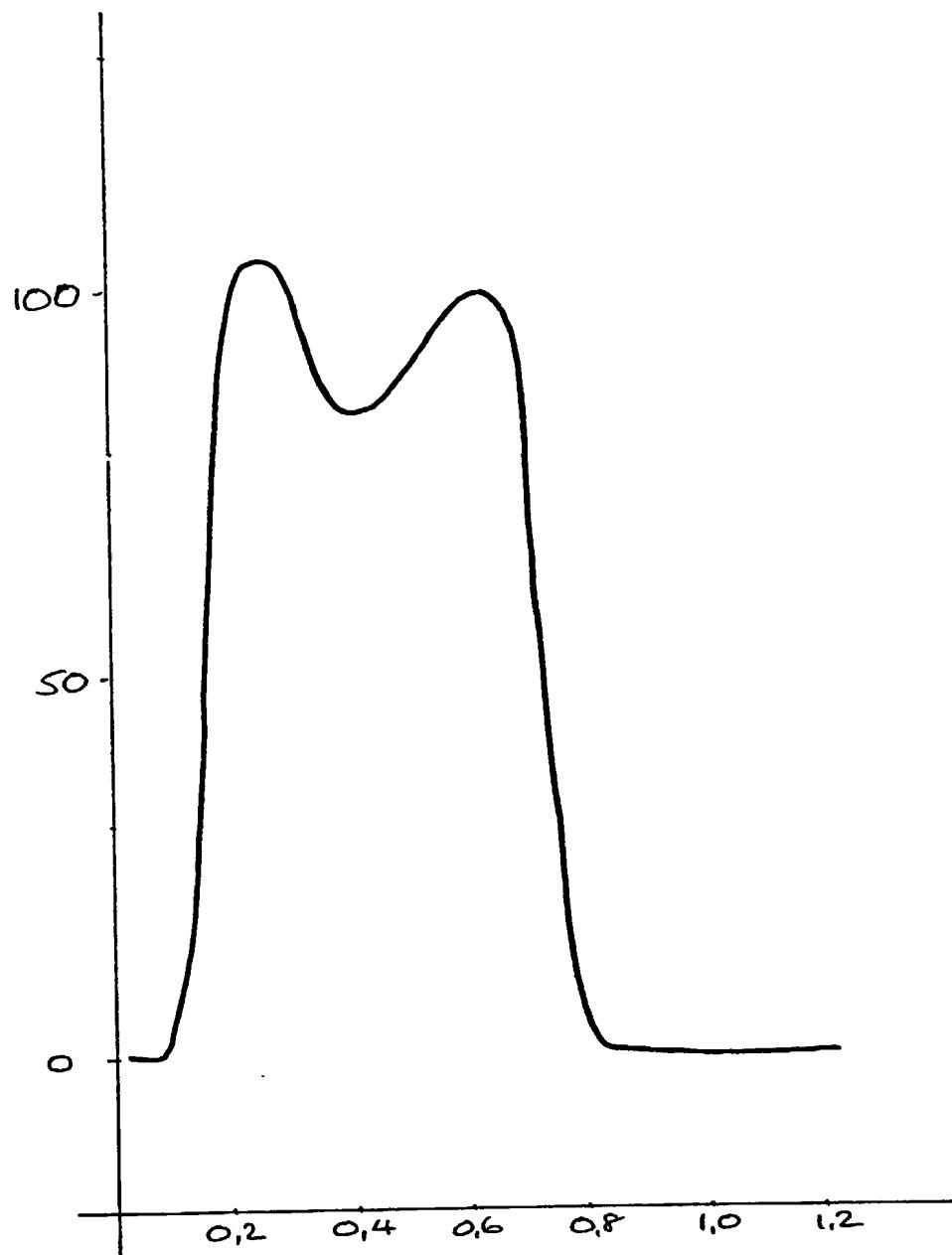


Fig 3

Docket No. 22748/1

## **COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor(s), I hereby declare that:

### **TYPE OF DECLARATION**

This declaration is for a patent application.

### **INVENTORSHIP IDENTIFICATION**

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if two or more names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### **ANKLE/FOOT ORTHOSIS**

### **SPECIFICATION IDENTIFICATION**

The specification

is attached hereto.

was filed on 3/1/02 and has U.S. Application Number 10/070,271  
and was amended on .

### **ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56.

## PRIORITY

The present application claims the benefit under 35 U.S.C. §119(a)-(d) of Prior Foreign Applications:

<b>Application Serial Number</b>	<b>Filing Date</b>	<b>Status</b>
9926599-3	11/11/1999	Abandoned
PCT/GB00/04288	11/08/2000	Pending

The present application claims the benefit under 35 U.S.C. § 119(e) of Prior U.S. Provisional Applications:

**Provisional Application Serial Number** **Filing Date**

The present application claims the benefit under 35 U.S.C. §120 of the following Applications:

**Application Serial Number** **Filing Date** **Status**

## **POWER OF ATTORNEY**

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

**APPOINTED PRACTITIONER(S)**

Brian L. Michaelis, Reg. No. 34-221  
Mark S. Leonardo, Reg. No. 41-433  
Barry C. Nelson, Reg. No. 46-954  
Maria Elisceva, Reg. No. 43-328  
John C. Serio, Reg. No. 39-023  
Mark A. Hofer, Reg. No. 30,068

David D. Lowry, Reg. No. 38,538-  
Peter B. Sorell, Reg. No. 44,349-  
Joseph P. Quinn, Reg. No. 45,029-  
John J. Penny, Jr., Reg. No. 36,984-  
Janice L. Kugler, Reg. No. P-50,429

All of Brown, Rudnick, Freed & Gesmer, One Financial Center, Boston, MA 02111; and

SEND CORRESPONDENCE TO

**DIRECT TELEPHONE CALLS TO:**

**Mark S. Leonardo**  
**Brown Rudnick Freed & Gesmer**  
**One Financial Center**  
**Boston, MA 02111**

**Mark S. Leonardo**  
**Phone: 617-856-8145**  
**Fax: 617-856-8201**

## **DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

*Shane Willard Nickson*

Inventor: Shane Willard Nickson

Inventor's signature: *S.W. Nickson*

Date 8 MARCH 2002

Country of Citizenship: Great Britain

Residence: 54 Glenorchy Road, Carterknowle, Sheffield S7 2EL, Great Britain

Post Office Address: Same as above

*Ceb 2*

#1091728 v\1 - #ds01!.doc - 22748/1